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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,054	12/16/2004	Chang-Ming Yang	YANG52	3511
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EXAMINER NAQI, SHARICK				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,054

Applicant(s)

YANG, CHANG-MING

Examiner

SHARICK NAQI

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Examiner acknowledges the amendment and Request for Continued Examination (RCE) filed December 17, 2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2 and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shusterman US Patent Publication Number 2003/0023146 in view of Davidson US Patent Publication Number 2004/0003455 and Heilman et al. US Patent Publication Number 2003/0158593 (hereinafter Heilman).

In regards to claim 1, Shusterman discloses a method of monitoring the physiological functioning and conditions of a person comprising

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the step of using sensors in a garment body worn by the person or biochips implanted in the person to continuously monitor the physiological functioning and conditions of the person (Shusterman, [0006, 0044]), and

the step of using a monitoring center unit (patient monitoring unit 214) to transmit monitored data to a proximity or remote control center (central station 100) through a communication port so that the user can interact with the monitoring center unit (Shusterman [0006, 0041, 0044]) or the user can have a two-way interaction with the remote control center, thereby providing related information to medical care persons at the remote side for diagnosis or giving an instruction to a person at the proximity side to take emergency measures.

Shusterman also teaches that the system includes sensors to determine when a patient has fallen (Shusterman [0083]).

Shusterman does not disclose the step of using at least two different types of medical treating devices mounted in predetermined zones of the garment body for applying medical treatments to the user wearing the garment body. However Davidson, a reference in an analogous art, discloses a wearable inflatable system that detects a fall using sensors and inflates multiple user-worn inflatable elements (inflatable elements are airbags thus they are equivalent to medical treatment devices mounted in predetermined zones of a garment body) to protect a falling body (Davidson [0009, 0017]). Davidson further teaches that the system adjusts the trajectory of the falling body, thereby avoiding dangerous falling positions (Davidson [0015]). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Shusterman that detects

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patient falls with Davison's disclosed step of providing a wearable fall protection system that inflates multiple user worn elements upon detecting a fall in progress with sensors because Davidson teaches that the fall protection system adjusts the trajectory of the falling body, thereby avoiding dangerous falling positions and protecting the user (Davidson [0015, 0017]).

Shusterman modified by Davidson discloses one type of medical treatment device in form of the airbags and also discloses ECG sensors to monitor a patient's cardiac activity (Shusterman [0092]). Shusterman modified by Davidson fails to disclose a second medical treatment device of a different type mounted in predetermined zones of the garment body for applying medical treatments to the user wearing the garment body. However Heilman, a reference in an analogous art discloses a cardiac garment with a wearable defibrillator (an electroshock device therefore equivalent to another medical treatment device mounted in predetermined zones of a garment body) that applies electric therapy to heart muscle if an arrhythmia is detected using ECG sensors (Heilman abstract and [0002 and 0010]). It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the method of Shusterman and Davidson that uses ECG sensors to monitor a patient's cardiac activity with Heilman's step of providing a wearable external defibrillator that uses the ECG data to apply electric therapy if an arrhythmia is detected because this permits the application of electric treatment to the heart muscle quickly and Heilman discloses that time delays in applying the corrective electrical treatment

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may result in death and the treatment is needed within a few minutes to be effective (Heilman [0005-0006]).

2. The method as claimed in claim 1, further comprising
the step of storing, managing and analyzing the monitored data for diagnosis for finding out abnormal conditions (Shusterman [0006, 0054]),
the step of using a display to enable the user to inquire the way to treat himself or to inform the medical care person taking care of the user when a syndrome showing degeneration of the physiological functioning of the user occurred (Shusterman [0053-0054, 0072, 0075]), and
the step of using a video camera to pick up the images of the user and to transmit monitored images to the remote control center through the communication port, for enabling the person in charge at the remote control center to determine the necessary measures (Shusterman [0063]).

In regards to claim 12, Shusterman discloses an apparatus for monitoring the physiological functioning and conditions of a user, comprising:

a garment body wearable to a user (Shusterman Figure 6);
first and second sensors mounted in the garment body for detecting the physiological functioning data and conditions of the user wearing the garment body (Shusterman, Figure 6 [0083-0088]);

a communication port for transmitting the physiological functioning data and conditions to a remote control center on the real time or at a delayed time or receiving and answering the inquiries of the user (Shusterman [0041, 0044]);

a monitoring center unit electrically connected with the sensors and the communication port for receiving and transmitting signals such that the communication port is used to transmitting the monitored data to the remote control center, the monitoring center having I/O ports connectable to the sensors and medical devices (Shusterman [0006, 0041, 0044, 0089]);

whereby the monitoring data of the user's physiological functioning and conditions is stored, managed and analyzed to find out abnormal conditions of the user for further treatments (Shusterman [0006, 0054]).

Shusterman also teaches that the system includes sensors to determine when a patient has fallen (Shusterman [0083]).

Shusterman does not disclose first and second medical treating devices mounted in the garment body for applying medical treatments to the user wearing the garment body, wherein the first and second medical treating devices are of different types of medical treating devices, spaced apart from each other and connected to the first and second sensors, respectively, the medical treating devices electrically connected to the monitoring center unit or communication port. However Davidson, a reference in an analogous art, discloses a wearable inflatable system that detects a fall using multiple sensors and inflates multiple user-worn inflatable elements (inflatable elements are airbags thus the different airbags are equivalent to a first type of medical treatment devices mounted in

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predetermined zones of a garment body, spaced apart and connected to first sensors) to protect a falling body (Davidson Figure 2, [0009-10, 0017]). Davidson further teaches that the system adjusts the trajectory of the falling body, thereby avoiding dangerous falling positions (Davidson [0015]). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the monitoring system of Shusterman that detects patient falls with Davison's wearable fall protection system that inflates multiple user worn elements upon detecting a fall because Davidson teaches that the system adjusts the trajectory of the falling body, thereby avoiding dangerous falling positions and protecting the user (Davidson [0015, 0017]).

Shusterman modified by Davidson discloses one type of medical treatment device in form of the airbags and also discloses ECG sensors to monitor a patient's cardiac activity (Shusterman [0092]). Shusterman modified by Davidson fails to disclose a second medical treatment device of a different type mounted in predetermined zones of the garment body and connected to a second sensor. However Heilman, a reference in an analogous art discloses a cardiac garment with a wearable defibrillator (an electroshock device therefore equivalent to another medical treatment device connected to second sensors mounted in predetermined zones of a garment body) that applies electric therapy to heart muscle if an arrhythmia is detected using ECG sensors (Heilman abstract and [0002 and 0010]). It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Shusterman and Davidson that uses ECG sensors to monitor a patient's cardiac

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activity with Heilman's feature of providing a wearable external defibrillator that uses the ECG data to apply electric therapy if an arrhythmia is detected because this permits the application of electric treatment to the heart muscle quickly and Heilman discloses that time delays in applying the corrective electrical treatment may result in death and the treatment is needed within a few minutes to be effective (Heilman [0005-0006]).

13. The apparatus as claimed in claim 12, wherein the garment body, first and second sensors and first and second medical treating devices are wearable by the user and removeable from the user as a single unit (Shusterman figure 6, Davidson figure 2 and Heilman figures 1a-b. It is the Examiner's position that the apparatus resulting from the combination of the three references would be capable of being worn and removed as a single unit).

Claims 14-17 are rejected on substantially the same basis as independent claim 12.

18. The apparatus as claimed in claim 12, wherein the first and second sensors are selected from the group consisting of pressure sensors, temperature sensors, terminal sensors, voice sensors, biochemical sensors and biochips (Shusterman, Figure 6 [0083-0088], Davison [0009-0010], Heilman Abstract).

Claims 3-5 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shusterman in view of Davidson US Patent Publication Number 2004/0003455.

In regards to claim 3, Shusterman discloses apparatus for monitoring the physiological functioning and conditions of a user, comprising:

a garment body wearable to a user, the garment body having a plurality of zones (Shusterman Figure 6);

sensors mounted in the zones of the garment body respectively for detecting the physiological functioning and conditions of the user wearing the garment body (Shusterman Figure 6, [0007]);

a communication port for transmitting the monitored data to a remote control center on the real time or at a delayed time or receiving and answering the inquiries of the user (Shusterman [0041, 0044]);

a monitoring center unit electrically connected with the sensors and the communication port for receiving and transmitting signals such that the communication port is used to transmitting the monitored data to the remote control center, the monitoring center having I/O ports connectable to the sensors (Shusterman [0006, 0041, 0044, 0089]);

whereby the monitoring data of the user's physiological functioning and conditions is stored, managed and analyzed to find out abnormal conditions of the user for further treatments (Shusterman [0006, 0054]).

Shusterman also teaches that the system includes sensors to determine when a patient has fallen (Shusterman [0083]).

Shusterman does not disclose medical treating devices connected to the monitoring center unit or communication port and mounted in predetermined zones of the garment body for applying medical treatments to the user wearing the garment body, wherein the medical treating devices are selected from the group consisting of oxygen source devices, pumps, air bags, body temperature regulators, pain-causing devices, hypodermic syringes and electroshock devices, wherein the air bags are of the type to correct the posture of the user, to fix a broken bone in position, to stop bleeding of blood, to apply cardio-pulmonary resuscitation or abdominal thrust (Heimlich maneuver) to the user. However Davidson, a reference in an analogous art, discloses a wearable inflatable system that detects a fall using sensors and inflates multiple user-worn inflatable elements (the inflatable elements are airbags thus they are equivalent to medical treatment devices mounted in predetermined zones of a garment body and they are capable of correcting the posture of the user as the user is falling) to protect a falling body (Davidson [0009, 0017]). Davidson further teaches that the system adjusts the trajectory of the falling body, thereby avoiding dangerous falling positions (Davidson [0015]). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the monitoring system of Shusterman that detects patient falls with Davison's wearable fall protection system that inflates multiple user worn elements upon detecting a fall in progress with sensors because Davidson teaches that the system adjusts the trajectory of the falling body, thereby avoiding dangerous falling positions and protecting the user (Davidson [0015, 0017]).

4. The apparatus as claimed in claim 3, wherein the sensors are selected from the group consisting of pressure sensors, temperature sensors, terminal sensors, voice sensors, biochemical sensors and biochips (Shusterman Fig 5).

5. The apparatus as claimed in claim 3, wherein the sensors produce signals corresponding to the physiological functioning and conditions of the user and send the signals to the communication port (Shusterman Fig 5, [0044]).

8. The apparatus as claimed in claim 3, wherein the air bag is supported on a bracket at the garment body for supporting the spine of the user wearing the garment body in shape (Davison [0015-0017]).

9. The apparatus as claimed in claim 3, wherein the communication port is connectable with a communication device to transmit monitored data to the remote control center for remote diagnosis, a computer or other compatible devices (Shusterman [0044]).

10. The apparatus as claimed in claim 3, wherein said monitoring center unit further comprises:

a sensor interface electrically connected to the sensors to transmit detected data to a processor for computing (Shusterman [0006-0007]);

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a communication port for transmitting detected data to the remote control center through a communication device for remote diagnosis, or to a computer or other compatible devices (Shusterman [0044]);

a data storage device for storing input data and detected data (Shusterman [0055]);

a display disposed at the garment body for displaying information (Shusterman [0088, 0095]); and

a power system for providing the apparatus with the necessary working electricity (Shusterman [0058]).

11. The apparatus as claimed in claim 3, further comprising means for data searching for enabling the monitoring center unit to be set for individual use subject to personal data inputted therein (Shusterman [0173, 0199]).

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shusterman, Davidson and Heilman as applied to claim 1 above and further in view of Starkweather et al. US Patent Publication Number 2001/0041920 (hereinafter Starkweather).

Shusterman, Davison and Heilman disclose that one of the biosensors is a glucose sensor (Shusterman [0092]). Shusterman, Davison and Heilman do not disclose that the sensor is implanted in the user. However Starkweather, a reference in an analogous art discloses that an external glucose sensor and an implanted glucose sensor are substitutable as means for determining glucose

levels (Starkweather [0051]). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Shusterman, Davidson and Heilman by substituting the external glucose sensor with Starkweather's implanted glucose sensor because Starkweather discloses that implanted and external sensors are substitutable as means for determining glucose levels of a patient (Starkweather [0051]).

Response to Arguments

Applicant's arguments filed December 17, 2008 have been fully considered but they are not persuasive.

Applicant argues that Shusterman and Davidson are not combinable because the sensors in Shusterman detect when a person has fallen whereas Davidson's sensors detect when a person is falling. The Examiner respectfully disagrees. It is the Examiner's position that it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Shusterman that detects patient falls with Davison's disclosed step of providing a wearable fall protection system that inflates multiple user worn elements upon detecting a fall in progress with sensors because Davidson provides motivation to do so by disclosing that the fall protection system adjusts the trajectory of the falling body, thereby avoiding dangerous falling positions and protecting the user (Davidson [0015, 0017]).

In regards to claim 3, applicant argues that Davidson's airbags do not disclose the following limitation, "wherein the air bags are of the type to correct

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the posture of the user, to fix a broken bone in position, to stop bleeding of blood, to apply cardio-pulmonary resuscitation or abdominal thrust (Heimlich maneuver) to the user." Examiner respectfully disagrees. The limitation of an airbag "to correct the posture of the user" is interpreted as intended use/functional language. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the Examiner's position that, Davidson's airbag is capable of correcting the posture of the user because Davidson's airbag adjusts the alignment of a back and a hip of body during a fall (Davidson Abstract).

Applicant's arguments regarding different types of treating devices and claim 19 are moot based on the new grounds of rejection provided above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARICK NAQI whose telephone number is (571)272-3041. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry M. Johnson III can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. N./

Examiner, Art Unit 3769

/Michael C. Astorino/

Primary Examiner, Art Unit 3769

March 12, 2009